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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: )  
)  
O'BRIEN et al. )  
)  
Serial No.: 10/715/066 )  
) Attorney Docket No.: 022438.45514  
No.: November 17, 2003 )  
)  
For: CA125 GENE AND ITS USE FOR )  
DIAGNOSTIC AND )  
THERAPEUTIC INTERVENTIONS )

TRANSMITTAL LETTER

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

The following documents for the above-captioned application are enclosed herewith:

1. Supplemental Information Disclosure Statement;
2. Information Disclosure Citation (PTO-1449), including references;
3. Return Post Card; and
4. Transmittal of Information Disclosure Statement (Under 37 CFR 1.97(b).

The Commissioner is authorized any deficiency or credit any payment due to our Deposit Account No. 50-0858. If you have any questions, please contact me.

Respectfully Submitted,

BUTLER, SNOW, O'MARA, STEVENS &  
CANNADA, PLLC

May 5, 2005  
Date

By: Susan B. Fentress  
Susan B. Fentress  
Reg. No. 31,327

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, on MAY 16, 2005, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

  
James D. Montgomery

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**

(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.

022438.4385

45514

In Re Application Of: O'Brien et al.

MAY 09 2005

Application No.

10/715/066

Filing Date

November 17, 2003

Examiner

Customer No.

28172

Group Art Unit

Confirmation No.

Title: CA125 Gene and Its Use for Diagnostic and Therapeutic Interventions.

Address to:

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**37 CFR 1.97(b)**

1. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

**37 CFR 1.97(c)**

2. ☐ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:

☐ the statement specified in 37 CFR 1.97(e);

**OR**

☐ the fee set forth in 37 CFR 1.17(p).

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT (Under 37 CFR 1.97(b) or 1.97(c))				Docket No. 022438.13365-4554											
Re Application: O'Brien et al.															
Application No. 10/715/066	Filing Date November 17, 2003	Examiner	Customer No. 28172	Group Art Unit	Confirmation No.										
Title: CA125 Gene and Its Use for Diagnostic and Therapeutic Interventions.															
<p align="center"><b>Payment of Fee</b> (Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))</p> <p><input type="checkbox"/> A check in the amount of _____ is attached.</p> <p><input checked="" type="checkbox"/> The Director is hereby authorized to charge and credit Deposit Account No. <u>50-0858</u> as described below.</p> <p><input type="checkbox"/> Charge the amount of _____</p> <p><input checked="" type="checkbox"/> Credit any overpayment.</p> <p><input checked="" type="checkbox"/> Charge any additional fee required.</p> <p><input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.</p> <p><b>WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</b></p> <table border="1"><thead><tr><th>Certificate of Transmission by Facsimile*</th><th>Certificate of Mailing by First Class Mail</th></tr></thead><tbody><tr><td>I certify that this document and authorization to charge deposit account is being facsimile transmitted to the United States Patent and Trademark Office (Fax No. _____)</td><td>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on <u>5/5/2005</u></td></tr><tr><td>(Date)</td><td>(Date)</td></tr><tr><td>Signature</td><td>Signature of Person Mailing Correspondence</td></tr><tr><td>Typed or Printed Name of Person Signing Certificate</td><td>Typed or Printed Name of Person Mailing Certificate</td></tr></tbody></table> <p>*This certificate may only be used if paying by deposit account.</p> <p><u>She B Earl</u> Signature</p> <p>Dated: <u>may 5, 2005</u></p>						Certificate of Transmission by Facsimile*	Certificate of Mailing by First Class Mail	I certify that this document and authorization to charge deposit account is being facsimile transmitted to the United States Patent and Trademark Office (Fax No. _____)	I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on <u>5/5/2005</u>	(Date)	(Date)	Signature	Signature of Person Mailing Correspondence	Typed or Printed Name of Person Signing Certificate	Typed or Printed Name of Person Mailing Certificate
Certificate of Transmission by Facsimile*	Certificate of Mailing by First Class Mail														
I certify that this document and authorization to charge deposit account is being facsimile transmitted to the United States Patent and Trademark Office (Fax No. _____)	I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on <u>5/5/2005</u>														
(Date)	(Date)														
Signature	Signature of Person Mailing Correspondence														
Typed or Printed Name of Person Signing Certificate	Typed or Printed Name of Person Mailing Certificate														



U.S. Application No.: 10/715,066

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: )  
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O'BRIEN ET AL. )  
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Serial No.: 10/715,066 )  
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Filed: November 17, 2003 )  
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For: CA125 GENE AND ITS USE ) Attorney Docket No.: 022438.45514  
FOR DIAGNOSTIC AND )  
THERAPEUTIC INTERVENTIONS )

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached Form PTO-1449.

Applicant respectfully requests that the Examiner consider the listed documents and indicate that it was considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that the listed documents are material or constitute "prior art." If the Examiner applies the document as prior art against any claim in the application and Applicant determines that the cited documents do not constitute "prior art" under United States law, Applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should the documents be applied against the claims of the present application.

**Document AA** – U.S. Patent No. 6,335,194 issued to Bennett et al. on January 1, 2002 discloses antisense compounds, compositions and methods for modulating the expression of Survivin. The compositions comprise antisense compounds, particularly antisense oligonucleotides, targeted to nucleic acids encoding Survivin. Methods of using these compounds for modulation of Survivin expression and for treatment of diseases associated with expression of Survivin are provided.

**Document BB**—U.S. Patent No. 6,451,602 issued to Popoff et al. on September 17, 2002 discloses antisense compounds, compositions and methods for modulating the expression of human PARP. The compositions comprise antisense compounds, particularly antisense oligonucleotides, targeted to nucleic acids encoding human PARP. Method of using these compounds for modulation of human PARP expression and for treatment of diseases associated with expression of human PARP are provided.

**Document CC** – Chambers J A et al., “Isolation of the Murine Nbr1 Gene Adjacent to the Murine Brcal Gene,” *Genomics* 15 December 1996, vol. 38, no. 3 (1996-12-15), pages 305-313, XP002301958 ISSN: 0888-7543. The abstract provides as follows: the human NBR1 has previously been identified using polyclonal sera to CA125, an ovarian tumor antigen used in monitoring ovarian cancer. The gene was mapped to the BRCA1 region on chromosome 17q21 and subsequently found to lie in close proximity to the recently identified BRCA1 gene. The NBR1 protein has a B-box motif but the function of the protein is as yet unknown. To investigate the function and importance of this gene, we have studied the conservation of this gene in other species and in particular in the mouse. We have isolated murine Nbr1 cDNA and genomic clones. Translation of the cDNA sequence indicated that the protein is highly conserved, being 89% similar and 84% identical to the human. Analysis of the murine Nbr1 genomic clones indicates that it maps less than 1 kb from the Brcal gene and that, unlike that in human, this region is not duplicated.

**Document DD** – O'Brien et al, “The CA 125 gene: a newly discovered extension of the glycosylated N-terminal domain doubles the size of this extracellular superstructure.” *Tumor Biology: The Journal of the International Society for Oncodevelopmental Biology and Medicine*. 2002 May-Jun, vol. 23, no. 3, May 2002 (2002-05), pages 154-169, XP008037160 ISSN: 1010-4283. The abstract provides as follows: CA 125 is a well-established marker for patients diagnosed with ovarian carcinoma. It is clearly elaborated in serous cystadenocarcinomas and less likely to be expressed in mucinous tumors. It has been 20 years since CA 125 was first recognized and it is only in recent years (the past 2) that some progress has been made toward cloning the gene, providing the basis for an understanding of the functional role of this molecule in embryonic development and neoplastic transformation. It is now clear that CA 125 is a large glycoprotein which is anchored to the epithelium by a transmembrane domain and is released into the extracellular space by enzymatic cleavage. Here, we describe a further major extension to the glycosylated extracellular amino terminal domain of this molecule. These additional data in association with our previous understanding of this molecule will provide the basis for our ability to understand the physiologic function of this molecule in biologic development and pathologic transformation.

**Document EE** – International Patent Application No. PCT/US99/30270 by Mitcham et al., published on June 22, 2000 discloses compositions and methods for the therapy and diagnosis of cancer, such as ovarian cancer, are disclosed. Compositions may comprise one or more ovarian carcinoma proteins, immunogenic portions thereof, polynucleotides that encode such portions or antibodies or immune system cells specific for such proteins. Such compositions may be used, for example, for the prevention and treatment of diseases such as ovarian cancer. Methods are further provided for identifying tumor antigens that are secreted from ovarian carcinomas and/or other tumors. Polypeptides and polynucleotides as provided herein may further be used for the diagnosis and monitoring of ovarian cancer.

**Document FF** – European Patent Application No. 88106516.3 by Timothy J. O'Brien, published on October 26, 1988 discloses a 40 kilodalton subunit of CA125 antigen, useful in the diagnosis and monitoring of ovarian cancer. It also relates to an immunoassay method for detection of the antigen in serum for diagnosis and monitoring purposes.

**Document GG** –International Patent Application No. PCT/US02/14768 by Lloyd et al. published on November 21, 2002 discloses an isolated nucleic acid molecule comprising sequences encoding the CA 125 protein or a portion thereof. This invention also provides a method to detect ovarian cancer in a subject. Furthermore, this invention provides a method for the diagnosis of a cancer which expresses CA 125 by detecting CA125-expressing cells in the blood or other fluids of patients. This invention also provides a method of producing CA 125 protein. Finally, this invention provides a method to treat or prevent cancer using a vaccine comprising CA 125 nucleic acid or protein.

**Document HH** – Database Genbank 1997, Robert Strausberg, Ph.d.: "EST name: nu02e01.s1" XP002301205 retrieved from NCBI. Database accession no. AA640762.

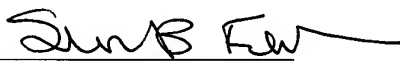
Applicant respectfully requests that the Examiner consider the listed documents and indicate that it was considered by making appropriate notations on the attached form.

In the event the Examiner has any questions regarding this document, please contact the undersigned at the telephone number listed below.

Respectfully Submitted,

Butler, Snow, O'Mara, Stevens &  
Cannada, PLLC

Date May 3, 2005

By:   
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U.S. Application No.: 10/715,066


CERTIFICATE OF MAILING

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Jim Montgomery

MEMPHIS 163925v1



 <p style="text-align: center;"><b>INFORMATION DISCLOSURE CITATION</b> (Use several sheets if necessary)</p>	Docket Number (Optional) <b>022438.45514</b>	Application Number <b>10/715,066</b>
	Applicant(s) <b>O'Brien et al.</b>	
	Filing Date <b>November 17, 2003</b>	Group Art Unit

U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	6,335,194	1-1-2002	Bennett et al.	435/375		2-2-2000
	BB	6,451,602	9-17-2002	Popoff et al.	435/375		3-2-2000

U.S. PATENT APPLICATION PUBLICATIONS							
*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS								
	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO
	EE	WO 00/36107	6-22-2000	PCT	C12N 15/			
	FF	88106516.3	10-26-1988	European	C07K 15/			
	GG	WO 02/092836	11-21-2002	PCT				

OTHER DOCUMENTS			<i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>
	CC	Chambers J A et al., "Isolation of the Murine Nbr1 Gene Adjacent to the Murine Brca1 Gene," Genomics 15 December 1996, vol. 38, no. 3 (1996-12-15), pages 305-313, XP0023001958 ISSN: 0888-7543.	
	DD	O'Brien et al., "The CA 125 gene: a newly discovered extension of the glycosylated N-terminal domain doubles the size of this extracellular superstructure." Tumor Biology: The Journal of the International Society for Oncodevelopmental Biology and Medicine, 2002 May-Jun, vol. 23, no. 3, May 2002 (2002-05), pages 154-169, XP008037160 ISSN: 1010-4283.	

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

# INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Docket Number (Optional)

022438.45514

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10/715,066

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Brien et al.

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Group Art Unit

\*EXAMINER  
INITIAL

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

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Database Genbank 1997, Robert Strausberg, Ph.d.: "EST name: nu02e01.s1" XP002301205 retrieved from NCBI. Database accession no. AA640762.

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.